Remarks

Claims 54-61 have been added, and therefore claims 20-61 are pending in this application. In view of the following remarks and the accompanying Declaration of Denise Zielanski establishing the commercial success of the claimed invention, it is respectfully submitted that these claims are allowable.

New independent claims 55 and 61 are commensurate in scope with the other independent claims; however, they are directed specifically to mammographic examination and claim 55 is written in means-plus-function format under 35 U.S.C. § 112, ¶ 6. No new matter has been added.

Pursuant to the Examiner's request, the continuing data on page 1 of the specification has been updated by amendment above, and the undersigned acknowledges that formal drawings are required and is endeavoring to file the formal drawings under separate cover.

Claims 1-19 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,469,847 to Zinreich et al., and in the alternative, stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,193,106 to DeSena. The Examiner's grounds for rejection are hereinafter traversed, and reconsideration is respectfully requested, particularly in view of the enclosed Declaration of Denise Zielanski establishing the commercial success of the claimed invention.

Zinreich et al. Do Not Teach Or Suggest The Claimed Invention.

Zinreich et al. does not teach or suggest providing a marker made of a partially radiopaque, partially radiolucent material, and generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail of the tissue

clearly visible through the radiographic shadow of the marker, as recited in the independent claims.

To the contrary, Zinreich et al. teach a multi-modality marker, i.e., one that can be used with multiple imaging methods, such as x-ray, CT, ultrasound, PET, MRI and others. (See col. 3, lines 5-11). For x-ray applications, Zinreich et al. specifically teach the use of radiopaque materials. More specifically, Zinreich et al. state that the gel 12 "is sufficiently *X-Ray-opaque* for adequate imaging on CT or X-Ray." (Col. 3, line 65 through col. 4, line 1; emphasis added). Zinreich et al. further teach that additional x-ray opaque materials may be used in addition to the radiopaque gel 12. Zinreich et al. specifically state: "an *X-Ray-opaque* metal, metallic powder or particles, or metallic salt (e.g., barium sulfate) may be laid into the outer casing 20 in addition to the gel 12." (Col., 6, lines 9-15; emphasis added).

Thus, Zinreich et al. in no way teach or suggest employing a partially radiopaque, partially radiolucent material in order to generate a radiographic image of the tissue with the shadow of the marker superimposed thereon, and the anatomical detail present in the tissue clearly visible through the radiographic shadow of the marker, as recited in the independent claims. Rather, it is only through impermissible hindsight reconstruction that one can assert that Zinreich et al. teach these claimed features of the invention. As summarized above, Zinreich et al. specifically teach forming the marker of a radiopaque material, and further teach placing the marker to the side of the tissue to be viewed, and generating either a "heavy, bright" or "heavy, dark" image of the radiopaque marker. Zinreich et al. state: "In images created from either MRI or X-Ray modalities (including CT) a marker 10 appears in side view as a *heavy, bright line* on a negative image or a *heavy, dark line* on a positive image. If the image is taken perpendicular to a

top surface 11 of the marker 10, the marker 10 appears as a *bright disk shape* on negative images or as a *dark disk shape* on positive images." (Col. 5, lines 4-9; emphasis added).

The passages in Zinreich et al. cited by the Examiner do not change this clear teaching away from the present invention. The passage at column 3, lines 2-5 of Zinreich et al. stating that the multi-modality surface markers "do not produce undesirable images which obscure portions of desirable images", is merely referring to the production of "streak artifacts" that occur when CT imaging with some prior art markers. This problem is also described, for example, in the "background" portion of the present application at page 2, lines 6-13. Moreover, the fact that Zinreich et al.'s markers may not produce streak artifacts (i.e., undesirable images that can obscure portions of other desirable images) in no way teaches or suggests the provision of partially radiopaque, partially radiolucent markers that allow anatomical detail falling within the marker's shadow to be clearly visible on the image, as recited in the independent claims.

DeSena Does Not Teach Or Suggest The Claimed Invention.

Like Zinreich et al., DeSena also is directed specifically to radiopaque markers. In each instance, DeSena's markers are described as "radiopaque". DeSena states: "Said marker devices 3 comprise a pressure sensitive adhesive medical tape 1 onto which a flexible *radiopaque* material is affixed." (Col. 4, lines 31-34; emphasis added). Similarly, DeSena describes the markers as "radiopaque" at col. 4, lines 52-54 ("the radiopaque material"), and column 5, lines 7-10 ("said radiopaque material"). Because DeSena's markers are radiopaque they would obscure radiographic detail if placed directly over the area of interest. Accordingly, DeSena further teaches forming the markers in perimeter shapes that "are large enough to *encompass* the region of interest". (Col. 3, lines 65-66; emphasis in original). Clearly, DeSena teaches avoiding the danger of obscuring radiographic detail not by making the marker partially radiolucent, as recited

in the present claims, but by placing the radiopaque marker around and outside of the area of interest. (See also col. 5, lines 7-11 and limitation "b" of claim 1 of DeSena). Thus, to modify the markers disclosed by DeSena in the manner suggested by the Examiner would be contrary to the express teachings of DeSena.

A significant advantage of the present invention is that the image of the partially radiopaque, partially radiolucent marker is superimposed over the image of the tissue with the anatomical detail present in the tissue clearly visible through the radiographic shadow of the marker, as recited in the independent claims. As a result, the marker cannot block the image of any underlying anatomical detail, nor can the image of the marker itself be mistaken for anatomical detail. Zinreich et al. and DeSena show no recognition of these problems, much less teach a solution to these problems as recited in the independent claims.

Although the Examiner asserts that it would have been obvious to adjust the thickness or percentage of attenuation of the markers shown in either Zinreich et al. or DeSena, the Office Action fails to point to any specific teaching in the prior art references of record suggesting modification of these prior art markers to be partially radiopaque and partially radiolucent, much less any teaching to generate radiographic images of the markers with anatomical detail of the tissue clearly visible through the shadow of the marker, as recited in the independent claims. Rather, it is only through the impermissible application of hindsight that one can assert that either Zinreich et al. or DeSena teach or suggest these claimed features of the invention.

The Commercial Success Of The Present Invention Dictates A Conclusion Of Non-Obviousness.

Evidence of secondary considerations of non-obviousness, including commercial success, "may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not." Ruiz v. A.B.

Chance Company, 2000 WL 17832367 (Fed. Cir. Dec. 6, 2000). Accordingly, the PTO must give secondary considerations -- including commercial success -- due weight in all cases where presented. In re Sernaker, 702 F.2d 989 (Fed. Cir. 1983).

As set forth in the attached Declaration of Denise Zielanski, an employee of the assignee of the present invention, Beekley Corp., the markers embodying the invention have enjoyed significant commercial success directly attributable to the claimed features of the invention. Accordingly, this evidence indisputably shows both the commercial success of the claimed invention, and the non-obviousness of the claimed invention over the prior art references cited by the Examiner.

As set forth in the Zielanski Declaration, the Beekley markers embodying the claimed invention are referred to by Beekley as "Light Image" markers because they are made of a partially radiolucent, partially radiopaque material that generates a radiographic image of the tissue having the shadow of the marker superimposed thereon, with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker, as recited in the independent claims of this application. (Zielanski Declaration at ¶ 2).

Beekley began selling the Light Image markers in 1996, and since then has sold the following three types of Light Image markers: Beekley's A-SPOTS® markers used for marking palpable masses (Exhibit A to the Zielanski Declaration), Beekley's O-SPOTS® markers used for marking moles (Exhibit B to the Zielanski Declaration), and Beekley's S-SPOTS® markers used for marking scars (Exhibit C to the Zielanski Declaration). As can be seen in the Exhibits to the Zielanski Declaration, Beekley's commercial products constitute the invention disclosed and claimed in this application (as opposed, for example, to being only a component of the commercially successful device), and therefore this in and of itself establishes a prima facie case

of nexus between the commercial success and the merits of the patented invention. Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387 (Fed. Cir. 1988), cert. denied, 488 U.S. 956 (1988).

As set forth in the Zielanski Declaration, Beekley has enjoyed considerable and ever-increasing commercial success in connection with these Light Image markers. Since 1997, Beekley's sales of these markers have been approximately as follows:

Product	**Number of Boxes**	**Number of Markers**	**Approximate Retail Dollar Value**
Light Image A-SPOTS	19,600	2,352,000	$1,038,800
Light Image O-SPOTS	77,347	4,486,126	$4,099,391
Light Image S-SPOTS	48,267	3,317,355	$2,558,151
Totals:	145,214	10,155,481	$7,696,342

Moreover, as further set forth in the Zielanski Declaration and reprinted below, Beekley has enjoyed continually increasing sales per year since introducing these Light Image markers:

Year	**Total Number Of Light Image Boxes**
1997	16,669
1998	32,974
1999	36,634
2000	42,001
2001 (first quarter only)	8936

(Zielanski Declaration at ¶s 3-5).

As set forth in paragraph 6 of the Zielanski Declaration, these substantial sales equate to a market share of greater than about 50% for the Beekley O-SPOTS® Light Image markers.

Accordingly, Beekley's Light Image markers constitute a significant and ever-increasing portion of the overall market for mammographic markers. Moreover, this substantial market share was obtained relatively immediately, i.e., within the first 3-4 years of product introduction. (Zielanski Declaration at ¶s 6 and 8).

Although the fact that Beekley's Light Image markers are coextensive with the claimed invention establishes the requisite nexus between the commercial success and the claimed invention, the Zielanski Declaration further establishes that the claimed features of the invention are the critical factor in motivating medical practitioners to purchase the markers of the invention. As set forth at paragraph 9 of the Zielanski Declaration, many of Beekley's Light Image marker customers previously refused to purchase and use skin markers because conventional radiopaque markers would block out anatomical detail present in the tissue underlying the marker. Accordingly, these customers only started using skin markers when Beekley's Light Image markers became commercially available, and such customers now regularly use the Light Image markers in their medical practices. (Zielanski Declaration at ¶ 9).

Moreover, prior to introducing the Light Image O-SPOTS and S-SPOTS markers, Beekley had manufactured and sold corresponding radiopaque markers. The only essential difference between these corresponding radiopaque and Light Image markers is that the Light Image markers are made of a material that allows imaging of the anatomical detail present in the tissue such that it is clearly visible through the radiographic shadow projected by the marker, as recited in the independent claims. (Zielanski Declaration at ¶ 3). Since introducing the Light Image markers, Beekley has sold substantially more Light Image markers than corresponding radiopaque markers. For example, in the year 2000, Beekley sold approximately 1.8 million O-SPOTS markers, and of these, approximately 1.3 million were Light Image O-SPOTS markers.

(Zielanski Declaration at ¶ 9). Accordingly, the commercial success of the Light Image markers is clearly attributable to the claimed features of the invention.

Moreover, although Beekley is not required to prove that the commercial success is not due to factors other than the claimed invention, this commercial success is clearly not the result of extensive advertising, nor is it the result of aggressive pricing or discounts. Rather, as set forth in the Zielanski Declaration, the Beekley Light Image markers are *more* expensive than substantially all competing markers. In addition, Beekley has initiated very little advertising in connection with the markers of the invention, but rather has marketed the invention almost entirely through product sampling. (Zielanski Declaration at ¶s 7 and 8).

It is therefore respectfully submitted that the clear evidence of commercial success, coupled with the reasons set forth above distinguishing the claimed invention from the cited references, indisputably shows that independent claims 20, 36, 46, 55 and 59 are unobvious in view of Zinreich et al. and DeSena for at least these reasons. Because claims 21-35, 37-45, 47-53, 54, 56-58, 60 and 61 each depend from, and therefore include all of the limitations of one of these independent claims, it is respectfully submitted that these dependent claims likewise are unobvious over the prior art references of record for the same reasons as the independent claims, and for reciting additional patentable subject matter.

Authorization is hereby given to charge our Deposit Account No. 50-1631 in the amount of $152.00 to cover the fee for the extra claims over 20 (2 independent claims at $40.00 per claim, and 8 additional claims in excess of 20 at $9.00 per claim). No fee in addition to those submitted herewith is believed to be required; however, if an additional fee is required, or otherwise if necessary to cover any deficiency in fees already paid, authorization is hereby given to charge our deposit account no. 50-1631.

If the Examiner wishes to further discuss any of the issues herein, or otherwise if it would facilitate the examination of this application, please call the undersigned at the telephone number below.

Respectfully submitted,

Date: June 1, 2001

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

45. (Amended) A method of radiographic examination as defined in claim 36, further comprising the steps of providing a plurality of said markers in predetermined shapes enhancing the information communicated by the markers, including:

(a) a first marker defining the shape of a circle [an arrow];

(b) a second marker defining the shape of a triangle; and

(c) a third marker defining the shape of a straight line [cross;

(d) a fourth marker defining the shape of a circle; and

(e) a fifth marker defining the shape of a straight line].

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